K981262

JUL 6 1998

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
CUSA EXCEL ULTRASONIC SURGICAL ASPIRATOR SYSTEM

I. Product Description:

The CUSA EXcel Ultrasonic Surgical Aspirator System is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissues while preserving vessels, ducts and other delicate structures. The CUSA EXcel System consists of a console which provides control and power functions, a surgical handpiece which provides ultrasonic mechanical energy to the surgical site, a titanium handpiece tip and flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA EXcel System accommodates most commercially available suction canisters, and specimen traps (optional). A two-pedal footswitch is provided with the console.

The CUSA EXcel System may be used with an external CUSA Electrosurgical Module (CEM), which will provide optional electrosurgical capability. The CEM module is a Force FX-8 Generator (FDA clearance was received for the Force FX Generator under K#944602). This provides the surgeon with the option of delivering cutting or coagulating current through the CUSA handpiece tip to the surgical site. The CEM function is controlled either with the Force FX-8 footswitch or by hand, using the CEM nosecone control button(s).

The main features of the CUSA EXcel Ultrasonic Surgical Aspirator System are as follows:

- Console is small and easy to move
- Small, lightweight, ergonomic handpiece (CUSA EXcel 36kHz Handpiece)
- Variety of tip diameters and lengths for specific surgical applications
- External CUSA Electrosurgical Module (CEM) provides optional electrosurgical capability and hemostasis
- Protective, flexible irrigation flue to shield the surgical tip and prevent trauma to surrounding tissue
- Simple to set-up and use
- CUSA EXcel Console is compatible with the currently marketed Valleylab CUSA PFT Ultrasonic 23kHz Straight Handpiece (C2500)
- Ability to change tips in a sterile surgical environment, such as a hospital operating room
- Preaspiration holes in the surgical tip minimize clogging and keep tip clear of debris
- Two-mode suction capability for open and laparoscopic procedures

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- Fast Flush mode flushes the operative site with irrigation fluid
- Coaxial fluid delivery to maintain cooling and irrigation at the surgical tip, and to efficiently remove debris for added visualization
- Includes TISSUE Select feature for control of fragmentation rate, and enhanced tactile feedback for added selectivity

II. Intended Use:

The CUSA EXcel Ultrasonic Surgical Aspirator System is intended for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including:

Neurosurgery
Gastrointestinal and Affiliated Organ Surgery
Urological Surgery
Plastic and Reconstructive Surgery
General Surgery
Orthopedic Surgery
Gynecological Surgery
Thoracic Surgery
Laparoscopic Surgery
Thoracoscopic Surgery

The system may also be combined with electrosurgery using the optional CUSA Electrosurgical Module (CEM).

III. Safety and Performance Data:

The CUSA EXcel Ultrasonic Surgical Aspirator System has been designed to conform with applicable sections of the following standards:

IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 601-2-2 (1991), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment
EN 60601-1-2 (1993) Medical Electrical Equipment, Part 1 General Requirements for Safety, 2 Collateral Standard: Electromagnetic Compatibility-requirements and Tests
IEC 801-3 (1984), Radiated Electromagnetic Field Requirements
ANSI/AAMI HF18 (1993), Electrosurgical Devices
CISPR11, Electromagnetic Compatibility for Industrial-process Measurement and Control Equipment: Emissions Requirements

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Validation and verification of the CUSA EXcel System will be accomplished through a combination of analysis and testing. This process will include a Risk Analysis and an electro/mechanical performance test on prototype units. The safe performance and proper function of the hardware and external controls of the CUSA EXcel Console will be tested (Note: the EXcel Console contains no microprocessor and no memory). The CUSA EXcel Handpiece and accessories will also be tested, both alone and in conjunction with the Console. The following is a summary of the testing to date, including test criteria, performed on the CUSA EXcel Console and the CUSA EXcel Handpiece. Testing has verified the safe performance and proper function of the product

The biological safety of the CUSA EXcel Ultrasonic Surgical Aspirator System devices has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Many of the materials used in the CUSA EXcel System are the same as currently used in Valleylab CUSA System 200 devices, which are legally marketed device(s); refer to Attachment 3 for a complete listing and 510(k) references. Those materials which are unique to the CUSA EXcel System are currently undergoing testing in accordance with ISO Standard 10993-1, Biological Evaluation of Medical Devices, Part 1 - Guidance on Selection of Tests, Device Category "External Communicating Device, Blood Path Indirect, contact duration A".

IV. Summary of Substantial Equivalence:

The CUSA EXcel Ultrasonic Surgical Aspirator System (Console, Handpiece, and Accessories) is substantially equivalent in function and intended use to the following legally marketed devices:

- Valleylab CUSA System 200 (510(k)'s K#921251, K#931902, K#934628) This console system operates at a frequency of 23kHz. The above submissions included 23kHz handpieces (CUSA PFT Ultrasonic Handpiece) and system accessories.

- Valleylab CUSA System 200H with 37kHz Handpiece (510(k) K#884413). This smaller handpiece operates at a higher frequency (37kHz) for applications which demand greater precision and user visibility.

A comparison chart of product features is located in Attachment 6. Included in Attachment 7 is a copy of the advertising literature for the CUSA System 200 Console and CUSA PFT Ultrasonic Handpiece.

The surgical indications outlined for the CUSA EXcel Ultrasonic Surgical Aspirator System (refer to section G. Intended Use) are identical to those indications which have been cleared by FDA in previous 510(k) submissions for the CUSA System 200 Ultrasonic Surgical Aspirators. Refer Attachment 8 for a

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listing of previous CUSA System 200 510(k) submissions cleared by FDA, and the indications for use associated with each submission. With all of these indications, the devices are intended to be used in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable. No additional surgical applications are requested for the CUSA EXcel System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 6 1998

Ms. Julie Ross
Senior Regulatory Affairs Associate
Valleylab, Inc.
5920 Longbow Drive
Boulder, Colorado 80301

Re: K981262
Trade Name: CUSA Excel Ultrasonic Surgical Aspirator System
Regulatory Class: II
Product Code: LFL, LBK
Dated: April 6, 1998
Received: April 7, 1998

Dear Ms. Ross:

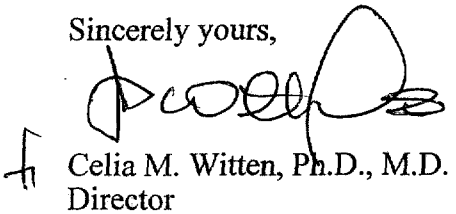
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number (if known): Not known at the time of submission

Device Name: CUSA EXcel Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA EXcel Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of General Restorative Devices
510(k) Number K981262

Prescription Use ✓ OR Over-The-Counter Use___
(Per 2.1 CFR 801.109)
(Optional Format 1-2-96)